**30231. Adulteration and misbranding of Edwenil. U. S. v. 355 Cartons, 221 Cartons, 205 Cartons, and 33 Cartons of Edwenil. Claim and answer filed. Amended libel filed. Claimant's exceptions to amended libel sustained. Second amended libel filed. Exceptions to second amended libel overruled. Claim and answer withdrawn. Default decree of condemnation and destruction.** (F. & D. No. 40019. Sample Nos. 37895–C, 38216–C to 38219–C, inclusive.)

This product was represented to be a polyvalent antibacterial agent, i. e., a drug which when administered hypodermically overcomes the activity of bacteria in the body of a living human being or animal. Examination showed that its standard was not that of a polyvalent antibacterial agent, but that it was inert. Its labeling bore false and fraudulent representations regarding its curative and therapeutic effectiveness.

On July 29, 1937, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 814 cartons, each containing 1 bottle of Edwenil, at New York, N. Y.; alleging that the article had been shipped in interstate commerce by Spicer & Co. from Glendale, Calif., within the period from on or about February 15, 1937, to on or about July 9, 1937; and charging adulteration and misbranding in violation of the Food and Drugs Act as amended. The original libel was amended August 24, 1937.

Analyses showed that the article consisted essentially of magnesium and nitrogenous compounds suspended in a solution of sodium chloride. It also showed total magnesium calculated as magnesium oxide (0.03 percent), total nitrogen calculated as protein (0.038 percent); sodium chloride (0.8 percent); phenol (0.45 percent); and a trace of silica.

It was alleged in the amended libel that the article was adulterated in that its strength fell below the professed standard under which it was sold, namely, a polyvalent antibacterial agent to be administered hypodermically with maximum doses of 4 cubic centimeters twice daily.

Misbranding was alleged in that the statement "A Polyvalent Antibacterial Agent," borne on the carton, was false and misleading since the article was not a polyvalent antibacterial agent, nor any antibacterial agent.

The article was alleged to be misbranded further because of false and fraudulent curative and therapeutic representations in the labeling, which were substantially the same as those quoted in the second amended libel referred to hereinafter.

On August 24, 1937, Spicer & Co., claimant, filed exceptions to the amended libel on the grounds that there was no allegation in the libel that the article was sold under a professed standard of strength; that the words "A polyvalent antibacterial agent" and the directions on the package did not constitute the professed standard of strength or purity within the meaning of the law, and that the said words constituted a statement regarding the curative or therapeutic effects of the article and not a statement of identity and prayed that the libel be dismissed. On August 31, 1937, the claimant's exceptions were sustained. On October 29, 1937, the Government's motion for rehearing was argued and was denied, and the amended libel was ordered dismissed with the following memorandum opinion:

PATTERSON, *District Judge.* "On reargument, I adhere to the opinion that the words complained of, in their meaning to the ordinary person, amount to a statement of therapeutic value and as now pleaded in paragraph 6 (a) of the amended libel are not a misbranding within the general paragraph of section 7. *United States* v. *Johnson*, 221 U. S. 488. The amended libel does not state that the product is sold to physicians and that to physicians the words give the product's identity. The affidavits handed up by the libelant purport to cover these points, but, of course, cannot receive affidavits where the motion is one to dismiss a pleading as defective on its face. The remedy of the libelant is to file a further amended libel embracing such allegations. The present amended libel will be dismissed, with leave to the libelant to file a second amended libel."

On November 16, 1937, a second amended libel was filed. Adulteration was alleged in the second amended libel in that the article was sold under a professed standard of strength, namely, the power of the article to protect certain animals from death when treated with measured doses of pneumococcus type II, or pneumococcus type III, as more fully set forth in a statement contained in a pamphlet entitled "The Endo toxic Infections and Their Control with Edwenil" (eleventh edition, published by Spicer & Co. in 1936) and an additional statement contained in a pamphlet entitled "Edwenil A Polyvalent Antibacterial Agent for the Endotoxic Infections," published by Spicer & Co. in 1937;

whereas the strength of the article fell below the said professed standard of strength.

The article was alleged to be misbranded in that it was advertised and sold primarily to members of the medical profession; that each of the said cartons bore the statement "Edwenil A Polyvalent Antibacterial Agent," that in the medical profession the term "polyvalent antibacterial agent" when applied to a drug has by usage become a term of identity describing and defining a drug made from serum from animals that have been immunized against several species of bacteria or from a mixture of sera from animals of which some have been immunized against one species of bacteria and others have been immunized against another species of bacteria; that the article was not made from serum or sera of the nature described hereinbefore, and that said statement on the carton was false and misleading. Misbranding was alleged further in that the following statements in the labeling regarding the therapeutic or curative effects of the article were false and fraudulent: (Carton) "A Polyvalent Antibacterial Agent * * * Usual dose: 2 cc. injected subcutaneously (See instruction slip inside)"; (instruction slip) "Dosage.—In acute infections and infectious diseases, as pneumonia or puerperal sepsis, 4 cc. twice a day from one to three days, then 2 cc. daily. To abort colds or influenza, 4 cc. once or twice or to effect. In chronic infections, * * * Give 2 cc. daily for a week, then 2 cc. every other day for several weeks. In infants and children, 1 or 2 cc. daily."

On March 25, 1938, the claimant's exceptions to the second amended libel were argued and were overruled with the following opinion:

BONDY, *District Judge.* "The libel alleges for a first cause of forfeiture that 'the article of drugs' referred to therein is sold under a professed standard of strength, and that the said professed standard of strength is the power of the article to protect certain animals from death when treated with measured doses thereof, as more fully set forth in statements contained in pamphlets published by the claimant, copies of which statements are annexed to the libel. It also alleges that the strength of the article falls below the said professed standard of strength.

"These allegations are sufficient to constitute a violation of the second paragraph section 7 of the Federal Food & Drugs Act (21 U. S. C. Sec. 8), which provides that a drug shall be deemed adulterated 'if its strength or purity fall below the professed standard of quality under which it is sold.'

"The claimant's sole contention is that the pleading is defective because it affirmatively appears therein that 'Edwenil is not sold under a professed standard of strength, but at most, is advertised under such standard.' The basis of this contention is the assertion that the statute is violated only when the professed standard of strength appears on or in the package or on the label.

"The libel, however, does allege: 'The said article is sold under a professed standard of strength.' It does not disclose that the alleged standard was not contained in the package of the article.

"Assuming, however, that the standard is proclaimed only in extrinsic advertising matter published by the claimant and not on the label or package or in any circular contained in the package, the libel is nevertheless sufficient. This conclusion is supported by the fact that the provisions of the act dealing with 'misbranding' are expressly limited to statements on the label or in the package; whereas the section under consideration does not contain any such limitation. It is entirely consistent with the language of the section that the standard be professed in advertising or other extrinsic media. The word professed is defined as 'openly declared, avowed, acknowledged or claimed.' (Webster) A declaration in an advertisement may be as much of an open avowal or profession of standard or quality as a statement on the label or package. The issue under the statute is whether the article has been sold under a professed standard; the place of profession is material only in determining whether the article actually has been sold under the standard.

"The claimant does not contend that a standard has not been professed in the statement annexed to the libel.

"The libel alleges as a second cause of forfeiture that the article is advertised and sold primarily to members of the medical profession; that each carton in which it is sold bears the statement 'Edwenil. A Polyvalent Antibacterial Agent'; that in the medical profession the term 'polyvalent antibacterial agent' when applied to a drug has by usage become a term of identity describing and defining a drug made from serum or a mixture of sera from animals that have been immunized against several species of bacteria; that the article is not made

from serum or sera of the nature described in the libel and that the statement is false and misleading.

"These allegations clearly are sufficient to constitute a violation of section 8 of the act (21 U. S. C. Sec. 9), which provides that misbranding shall apply to all drugs the package or label of which shall bear any statement regarding such article which shall be false or misleading in any particular. See *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, 442, 443.

"The exceptions accordingly are overruled."

On April 19, 1938, the claimant filed an answer to the second amended libel, and on May 6, 1938, an amended answer. On December 29, 1938, the claimant moved to withdraw its appearance, claim, and answer, which motion was granted; and on January 18, 1939, judgment of condemnation was entered and the product was ordered destroyed.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

**30232. Adulteration and misbranding of Edwenil. U. S. v. 790 Cartons of Edwenil (and 1 other seizure action against the same product). Consent decrees of condemnation and destruction.** (F. & D. Nos. 40035, 40129. Sample Nos. 15192–C, 15194–C.)

The labeling of this product and its composition was essentially the same as that covered by the product in notice of judgment No. 30231.

On August 4 and 20, 1937, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of 1,895 cartons of Edwenil at Chicago, Ill.; alleging that the article had been shipped in interstate commerce by Spicer & Co. within the period from on or about January 6 to on or about July 16, 1937; and charging adulteration and misbranding in violation of the Food and Drugs Act as amended.

The article was alleged to be adulterated in that its strength fell below the professed standard under which it was sold, namely, "A Polyvalent Antibacterial Agent," since it was not a polyvalent antibacterial agent.

The article was alleged to be misbranded in that the statement in the circular and on the carton, "A Polyvalent Antibacterial Agent" was false and misleading. It was alleged to be misbranded further in that certain statements on the carton and in an accompanying circular contained false and fraudulent representations regarding its effectiveness as a polyvalent antibacterial agent, its effectiveness in acute infections and infectious diseases such as pneumonia or puerperal sepsis, and its effectiveness to abort colds or influenza; and in that certain statements in a circular accompanying a portion of the article bore false and fraudulent representations regarding its effectiveness as a stimulant to the production of lysins or antibodies which lyse or destroy the endotoxic bacteria; its effectiveness to increase the quantity of these antibodies and speed their mobilization; its effectiveness in acute diseases of the respiratory system (especially pneumonia), sepsis, cellulitis, carbuncles, and skin infections; and its effectiveness to increase bacteriolysis and increase pus production.

On February 8, 1939, Spicer & Co., claimant, having withdrawn its appearance and having consented to the entry of decrees, judgments of condemnation were entered and the product was ordered destroyed.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

**30233. Adulteration and misbranding of aspirin tablets. U. S. v. 23 Bottles and 17 Bottles of Aspirin Tablets. Default decree of condemnation and destruction.** (F. & D. Nos. 44533, 44534. Sample Nos. 9191–D, 9192–D.)

These tablets were represented to contain 5 grains each of aspirin (acetylsalicylic acid), but contained approximately 4½ grains. They failed to conform to the standard prescribed in the National Formulary, since that authority requires that tablets of acetylsalicylic acid shall contain not less than 92.5 percent of the labeled amount of the drug.

On or about December 21, 1938, the United States attorney for the Southern District of Texas, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 40 bottles of aspirin tablets at Houston, Tex.; alleging that the article had been shipped in interstate commerce on or about May 18, 1938, by the Charles H. Dietz Co., from St. Louis, Mo.; and charging adulteration and misbranding in violation of the Food and Drugs Act.

Adulteration was alleged in that the article was sold under a name recognized in the National Formulary, but differed from the standard of strength, quality, and purity as determined by the tests laid down therein, and its own standard